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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/587,049	06/02/2000	KAZUHIKO AMANO	P2292.D1	6603

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EXAMINER	
NASSER, ROBERT L	
ART UNIT	PAPER NUMBER
3736	

DATE MAILED: 09/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/587,049	Amano et al
Examiner	**Art Unit**
Robert Nasser	3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *phone conversation of August 28, 2002* .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above, claim(s) *26-30* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-8, 10-14, 16, 17, 19, and 21-25* is/are rejected.

7) ☒ Claim(s) *9, 15, 18, and 20* is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *2,7*
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

This action is being re-sent per applicant's request, as applicant indicated that no McNally reference had been provided by the examiner.

Applicant's election of Group I, Claims 1-25 in Paper No. 6 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Accordingly, claims 26-30 are withdrawn from consideration.

Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The end of the claim recites "during a specified time period over a specified time period." The appears to be redundant.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 4, and 10 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Cosgrove Jr. et al.

Claims 1-4 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by NcNally et al. McNally teaches a system that has a sensor to monitor a parameter indicative of arousal or sedation (blood pressure) and produce a signal, means to processing the signal to control a drug delivery device to deliver a drug to the patient, by comparing the current signal with a stored parameter indicative of the desired state and either sedate the patient when the signal indicates arousal or arouse the patient when the signal indicates sedation. The drug delivery device is an infuser.

Claims 13, 14, 16, 17, and 25 are rejected under 35 U.S.C. 102(e) as being anticipated by Amano et al 5,730,137. Amano shows a device that has a sensor to detect blood pressure or heart rate, a memory to store the blood pressure or heart rate signals, control means to determine when to administer a drug based on the rhythm of the blood pressure or heart rate, and a drug administration means, which is an infuser, to administer the drug.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over McNally et al in view of Samiotes et al. Samiotes teaches not allowing drug delivery until a predetermined time has passed since the last drug delivery to prevent overdosing of the patient. Hence, it would have been obvious to include such a monitor in Amano et al to prevent patient injury.

Claims 6-8, 11, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over McNally et al in view of Sherer. Sherer further teaches recording the time of drug delivery, type of drug delivered etc to provide the physician with a complete record of the treatment. Hence, it would have been obvious to modify the McNally to use such a storage means, to keep the patient's treatment record up to date. With respect to claims 11 and 12, the examiner notes that Sherer monitors both blood pressure and heart rate to ensure that the patient gets all of the required treatment. Hence, it would have been obvious to modify McNally to also measure pulse rate, to provide a complete care package to the patient.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Amano et al in view of Falcone et al 5,464,012. Falcone further teaches that large changes from a running average value of a parameter are also a cause for concern and must be treated. Hence, it would have been obvious to modify Amano to respond to big changes b infusing drugs, to keep the levels constant.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Amano et al in view of Valcke et al. Valcke further teaches sounding an alarm when the total amount of the drug

administered reaches a set amount, to prevent over dosing the patient. Hence, it would have been obvious to modify Amano et al to include such an alarm , to prevent injury to the patient.

Claims 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Amano et al in view of Valcke et al as applied to claim 21 above, and further in view of Coutre et al. Coutre et al further teaches s monitoring the operating condition of a drug infusion system and sounding alarms when the system is not operating correctly. Hence, it would have been obvious to modify Amano et al to use such a system monitor, to ensure proper system operation and proper patient treatment.

Claims 9, 15, 18, and 20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. .

Bourland et al, Palti, and Pfeiler et al show other systems that control drug delivery based on patient physiological parameters.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert L. Nasser Jr. whose telephone number is (703) 308-3251. The examiner can normally be reached on Monday-Thursday and alternate Fridays from 8:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver, can be reached on (703) 308-2582. The fax phone number for this Group is (703) 308-0758.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [kevin.shaver@**uspto.gov**].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0858.

RLN
September 11, 2002

Robert L Nasser

ROBERT L. NASSER
PRIMARY EXAMINER